

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

FEDERAL TRADE COMMISSION,

Plaintiff,

v.

DIRECT MARKETING CONCEPTS, INC., et
al.,

Defendants.

CIVIL ACTION NO. 04-CV-11136GAO

**THE DMC DEFENDANTS' OPPOSITION TO
PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT**

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DIRECT, INC., DONALD W. BARRETT, and
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**DEFENDANTS' OPPOSITION TO
PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT**

Defendants, Direct Marketing Concepts, Inc. ("DMC"), ITV Direct, Inc. ("ITV"), Donald W. Barrett ("Barrett") and Robert Maihos (collectively "DMC Defendants"), submit this opposition to the Plaintiff Federal Trade Commission's ("FTC" or "Plaintiff") motion for summary judgment against the DMC Defendants. Because there are material issues of disputed fact on virtually every issue argued by the FTC, the FTC's motion must be denied.

PRELIMINARY STATEMENT

Disputed issues of material fact permeate the FTC's motion for summary judgment. In its 77 page statement of "undisputed" facts, the FTC's own evidence directly contradicts the statements of fact asserted by the FTC, necessitating a trial of these issues. These disputed issues of fact go to each and every aspect of the FTC's motion, including the facts surrounding the creation of the subject advertising, who distributed and profited from the subject advertising, whether the subject advertising is in fact false or misleading, the existing scientific support for the claims in the advertising, the responsibilities of the DMC Defendants in connection with the advertising, whether any consumers were actually misled or harmed by the conduct alleged by the FTC, and whether there is any continuing harm warranting the drastic relief sought by the FTC.

Given the volume of disputed facts in the record, there are numerous open questions regarding whether the DMC Defendants are liable for any of the claims asserted by the FTC. These questions can only be answered with a trial. For example, in connection with the original coral calcium infomercial, the DMC Defendants acted only as a "call center" in connection with the show, and did not themselves produce or edit the show, appear in the show, purchase media for the show, purchase any products in connection with the show or receive any funds from

customers. Moreover, the DMC Defendants did not themselves make any false or deceptive representations in either of the challenged infomercials, which in any event were accompanied by clear disclaimers stating that the products were not a cure for any disease. The record also demonstrates that the DMC Defendants reasonably relied upon express representations from the subjects of both infomercials that they could substantiate each and every opinion expressed by them in the infomercial, and were provided materials by each of the subjects that appeared to substantiate their opinions. As the Ninth Circuit recently held in *FTC v. Garvey*, 383 F.3d 891, 902 (9th Cir. 2004), a defendant is not required to prove that he or she relied upon evidence that “conclusively establishes” the efficacy of a product, but rather only that the materials contain “significant, relevant” information. The FTC has failed to overcome its burden of demonstrating that there is no issue of fact concerning the reasonableness of the DMC Defendants’ reliance, particularly given their role in the advertising.

There is also a significant dispute regarding the alleged falsity of the shows themselves. In light of the protections afforded commercial speech by the First Amendment to the United States Constitution, the Court must consider the overall context of any advertising challenged by the FTC, including whether the statements are expressed as opinions or fact, the available substantiation for those opinions, and the existence of disclaimers. In fact, even if advertising admittedly is inherently misleading, it may still be protected if coupled with adequate disclaimers. Here, the FTC has failed to overcome its burden to demonstrate there is no factual dispute regarding a material element of its *prima facie* case with supporting evidence, namely that the infomercial is actually misleading to reasonable consumers in light of the accompanying disclaimers. The FTC has also failed to overcome the significant factual dispute regarding the opinions expressed in the infomercial itself and the available scientific literature supporting those

opinions. Although the FTC argues that the testimony of its third party “experts” is uncontested, the DMC Defendants have placed before the Court a wealth of evidence that directly undermines the opinions and conclusions of these experts, including a substantial volume of scientific literature and studies. These studies, some of which are cited by the FTC’s experts themselves, demonstrate that there are genuine issues regarding the scientific support for the opinions expressed in the subject advertising, requiring a trial.

Finally and most importantly, the FTC repeatedly claims that it is “undisputed” that consumers were misled and harmed in connection with the subject advertising. However, the FTC has failed to submit even a single customer complaint or affidavit stating that any customer was actually misled by the challenged advertising. This failure is not immaterial, but demonstrates that the FTC has not, and cannot, overcome its burden as to a required element of its *prima facie* case. Thus, even if the FTC could show that the DMC Defendants were responsible for the opinions of others expressed in the subject advertising, which is strongly disputed by the DMC Defendants, absent some evidence that consumers were actually harmed or misled, the FTC’s motion must be denied.

I. STATEMENT OF FACTS AND PROCEDURAL HISTORY

DMC and ITV Direct, located in Beverly, Massachusetts, are media and marketing companies that collectively employ over 350 individuals in Massachusetts. DMC Defendants’ Statement of Disputed Facts (“SDF”), ¶¶ 7-8. DMC’s and ITV Direct’s business includes the production of infomercials, in which an individual is provided the opportunity to discuss an existing product to a larger audience through wider media, including television and radio. *Id.* Neither DMC nor ITV itself manufactures any products. *Id.* In connection with any agreement entered into by the DMC Defendants to produce an infomercial for a third party, DMC and ITV Direct make clear that the individual advertising the product is responsible for each and every

representation he makes about a product, including confirming that he has competent and reliable scientific support for any claims made about the product. SDF, ¶¶ 26, 68, 166-179, 265, 348-362. DMC and ITV Direct require that the individual provide specific scientific evidence and support for their claims, and provide indemnification to DMC and ITV for any claims and opinions expressed in the infomercial. *Id.*

In 2001, DMC's President Donald Barrett heard a radio program featuring Robert Barefoot, who had written a book claiming that a dietary supplement known as coral calcium had substantial health benefits. SDF, ¶¶ 10, 68. In his book and in other conversations, Barefoot cited to significant research, studies, documentation, testimonials and other scientific information, to support his claims concerning the health benefits of coral calcium. SDF, ¶ 68. Believing that a televised advertisement featuring Barefoot could be successful, Barrett contacted Kevin Trudeau, one of the most famous talents in the infomercial business, and suggested that he consider producing a program featuring Barefoot and Trudeau. *Id.* Barrett also provided Trudeau with an existing tape of a televised program produced by Barefoot. *Id.* After Trudeau responded that he believed such a program could be successful, Barefoot flew to California to Trudeau's studio to tape the program, in which Trudeau and Barefoot discussed Barefoot's book and the benefits of coral calcium. SDF, ¶ 72-80. The taping of the infomercial was entirely unscripted, and DMC did not appear in the infomercial or control any of its content. SDF, ¶¶ 10, 68, 81.

Upon completing the taping of the program in California, Trudeau maintained all raw footage of the program and took over control of producing the show, editing the show for content and completing a final "master" tape. Trudeau told Barrett and Barefoot that he would have his staff, including scientific experts and attorneys, review the program for content and compliance,

before the final tape was released for distribution. SDF, ¶ 72-80. Barefoot then coordinated with Trudeau's counsel and experts, providing them substantial materials in support of the advertisement, in addition to the materials cited in his book. *Id.* Upon completing the master tape, it was then provided to Triad ML Marketing, King Media and Allan Stern for distribution to media outlets, after further assurances were provided that the tape was compliant. Neither DMC nor Barrett had any involvement in editing the tape, purchasing media time for the program, purchasing books or product, or receiving customer funds. Rather, DMC's sole role in connection with the show was to act as a "call center" to receive incoming calls from the show for a fee, and forward all orders to Triad for processing. SDF, ¶¶ 10, 11, 69-71, 72-80, 83, 84-86, 99-107. On several occasions, Stern confirmed to Barrett that he had also provided the tape to his counsel for review, and that there were no problems with the content of the show. SDF, ¶ 83, 108-109.

The FTC received a tape of the infomercial in or about April 2002, and never notified the DMC Defendants that it had any issues or concerns over the content of the infomercial until over a year later, in June 2003. At this time, the FTC brought an action in the federal court in Illinois against Trudeau and Barefoot. SDF, ¶ 2. According to the FTC, Trudeau netted total revenues in excess of \$120 million from the show. *Id.* The FTC ultimately settled with Trudeau for a total payment of \$2 million, and settled with Barefoot for no payment whatsoever. *Id.*

In response to the FTC's concerns, the DMC Defendants obtained copies of many of the studies and supporting documentation that Barefoot had assured them existed. These studies, in addition to the citations in Barefoot's books and hundreds of other studies that the DMC Defendants have obtained, do appear to support the opinions expressed in the infomercial. Nonetheless, DMC agreed to immediately cease any future airings of the coral calcium

infomercial in June 2003, and that infomercial has not been aired by the DMC Defendants since that time. SDF, ¶¶ 132-161.

In late 2002, the DMC Defendants were contacted by defendant Gregory Geremesz (“Geremesz”), who stated that he knew a “Dr. Alejandro Guerrero” (“Guerrero”), who had developed a greens product named Supreme Greens that Geremesz believed would likely be successful if marketed through an infomercial. SDF, ¶¶ 15, 166-168. Barrett and others at DMC had previously learned of Guerrero through a seminar hosted by motivational speaker Tony Robbins, who had stated that Guerrero was a successful doctor of alternative and Eastern therapies, who operated a clinic in California. *Id.* The DMC Defendants reviewed the materials provided by Geremesz, and then met with Geremesz and Guerrero, who represented that he was a doctor and OMD (doctor of oriental medicine). Guerrero also confirmed that he operated a clinic in California with regular patients. SDF, ¶¶ 166-168, 171-179. Geremesz and Guerrero also represented on numerous occasions that the greens product developed by Guerrero had been clinically tested on over 200 patients in California and had shown tremendous results, including on patients with cancer, AIDS, MS, diabetes and Parkinson’s disease. *Id.* On the basis of these representations, scientific materials that were provided, and the promise that additional supporting documentation would be provided upon request, ITV agreed to produce an infomercial featuring Guerrero. SDF, ¶ 183-186. As is the case with all of ITV’s infomercials, the session with Guerrero was unscripted, and merely posed questions to Guerrero and elicited his responses in the form of his opinions. SDF, ¶ 171-179. Neither Barrett nor any other ITV employee dictated any of the statements by Guerrero in the infomercial, including his statements regarding his credentials, his clinical practice or the scientific support for Supreme Greens. *Id.*

In addition to the opinions expressed by Guerrero, and the materials that he had provided, the infomercials and all promotional materials for Supreme Greens had express disclaimers, clearly stating that results could vary and that the product was not a cure for any disease. SDF, ¶ 188-194. The infomercial also disclosed that ITV was not confirming or attesting that there existed any scientific support for the opinions expressed by Guerrero. *Id.* These disclaimers ran throughout the infomercials, and were also required by the networks who ran them. *Id.* In addition to these disclaimers, ITV also received indemnification from Guerrero's company Healthy Solutions for the opinions expressed in the infomercial. SDF, ¶ 169-170. The DMC Defendants have never themselves manufactured the Supreme Greens product, and all of the labeling and related information was provided directly by Healthy Solutions. SDF, ¶ 164-165.

During September and October 2003, the DMC Defendants' counsel was contacted by the FTC concerning the Supreme Greens infomercial. In those conversations, the FTC identified several concerns with the content of the infomercial. SDF, ¶ 209-231. In response to these concerns, the DMC Defendants both sought additional scientific evidence from Guerrero and Healthy Solutions, and edited the program to address the FTC's concerns. *Id.* These edits included the editing of content and the addition of additional disclaimers. In October 2003, the edited tape was sent to the FTC, and the FTC concluded that the edited tape was a "substantial improvement." *Id.* ITV then distributed the edited, "substantially improved" tape to national markets, and then to local markets. *Id.* ITV also received additional materials from Guerrero to substantiate the claims he made in the infomercials, including "double blind" studies and similar scientific information, and over time has collected substantial additional materials providing substantiation for the show. SDF, ¶¶ 183-186, 243-265. Guerrero also promised to provide the patient studies from his California clinic, but stated that he needed to confirm with his counsel

that he was not breaching any patient confidentiality laws by disclosing these materials. SDF, ¶ 169-170.

Between December 2003 and April 2004, the FTC had no communications with the DMC Defendants or its counsel. Beginning in March 2004, ITV voluntarily began reducing its media purchases for Supreme Greens, with the intention of pulling the infomercial completely by June 2004. On April 7, 2004, the FTC informed the DMC Defendants that it continued to have concerns over the Supreme Greens infomercial and that it believed that the original infomercial was running in certain media markets. The DMC Defendants investigated the matter and immediately notified all media outlets to cease running any of the Supreme Greens versions. ITV disputes that it ever intentionally ran the unedited version or instructed stations to do so, and disputes the FTC's misleading and incorrect interpretation of certain documents to support that claim. SDF, ¶ 209-231. To the contrary, upon reviewing the FTC's concerns, and in light of its previous decision to cease running the infomercial, ITV halted all media purchases for Supreme Greens, and the show has not run since May 2004.¹

Notwithstanding their agreement to cease running the coral calcium and Supreme Greens infomercials, the DMC Defendants have since sought to collect independent research and scientific support for the opinions expressed in both programs. This research and support demonstrates that many of the opinions expressed by Barefoot and Guerrero do have substantial support in the scientific literature. SDF, ¶¶243-265. These studies also demonstrate that the FTC's claims that there is *no* such support in *any* of the literature is simply not true. *Id.*

¹ As a result of the FTC's concerns, in April 2004 the DMC Defendants conducted their own investigation of Guerrero. Based on this investigation, ITV was informed that it appeared that Guerrero is not a doctor, and that he never received a doctorate of any kind. It also appeared that contrary to his repeated representations and assurances, Guerrero did not possess the clinical support for the health claims he made about Supreme Greens. On this basis, the DMC Defendants sought indemnification from Guerrero in connection with the FTC's investigation and any possible remedies it may seek in this action pursuant to their rights under their contract with Guerrero.

Regardless of who is ultimately correct, the existence of this wealth of scientific substantiation, along with the decision by the FDA subsequent to the filing of this suit to allow certain cancer claims in connection with calcium supplements, creates issues of fact that cannot be resolved on a motion for summary judgment.

In addition to the disputed facts surrounding the advertising itself, the DMC Defendants dispute the FTC's evidence regarding alleged improper sales practices. Rather than supporting the FTC's arguments, this evidence affirmatively undermines those arguments. Moreover, the DMC Defendants have taken significant steps over the last several years to improve compliance and assure that all sales practices and interactions with customers meet the highest ethical and business standards. In addition, the DMC Defendants have hired in-house legal counsel to oversee all legal and compliance aspects of the sales process, improved the effectiveness of its Contract Genie, which records all customer calls in which a continuity order is received, hired a dedicated compliance supervisor on its sales floor to review these recordings and monitor sales calls, improved communication of the company's strict policies regarding the continuity program, and increased discipline for those that violate the policy. SDF, ¶¶269-279, 285-287, 305-311. It is DMC's and ITV's clearly stated policy to require all sales personnel to disclose to customers the terms of any of their programs, including the auto ship program, fully and clearly. *Id.* It is also ITV's stated policy to fully disclose, both orally and in written materials, its return policy and the right for a customer to receive a refund at any time. If a sales representative is discovered violating these policies, it is the company's policy to discipline the employee, including termination if warranted. SDF, ¶ 312-318.

In addition, each infomercial produced by the DMC Defendants, particularly those advertising any dietary supplement, are required to undergo a stringent process of review, as to

content, claims, disclaimers and scientific support. SDF, ¶¶ 348-362. Each and every infomercial produced by the DMC Defendants or associated with the DMC Defendants has at least two separate oral and written FDA disclaimers, and has the required disclaimers identifying the infomercial as a paid advertisement. *Id.* The shows are also reviewed by counsel, and the company's scientific adviser. If necessary, the DMC Defendants also request an affidavit or report from a scientific expert or medical doctor. *Id.* In short, while the DMC Defendants maintain there are significant disputed issues of fact in connection with their liability for the infomercials that are the subject of the present complaint, which have not been aired since 2003 and 2004, respectively, they have continued to improve their compliance and controls and take these responsibilities very seriously.

II. LEGAL ARGUMENT

“Summary judgment is appropriate only where there are no genuine disputes concerning any material facts, and the moving party is entitled to judgment as a matter of law.” *FTC v. P.M.C.S., Inc.*, 21 F.Supp.2d 187, 191 (E.D.N.Y. 1998). See *Fenton v. John Hancock Mutual Life Ins. Co.*, 400 F.3d 83, 87 (1st Cir. 2005); *Kennedy v. Josephthal & Co., Inc.*, 814 F.2d 798, 804 (1st Cir. 1987) (summary judgment appropriate only where “there is not the slightest doubt as to whether a genuine issue of material fact exists”). “In deciding a summary judgment motion, the district court must resolve all ambiguities and draw all reasonable inferences in the light most favorable to the opposing party.” *FTC v. P.M.C.S., Inc.*, 21 F.Supp.2d at 191 (citing *Holt v. KMI-Continental, Inc.*, 95 F.3d 123, 128 (2d Cir. 1996), *cert. denied*, 520 U.S. 1228 (1997)). See *Milesi v. United States*, 946 F. Supp. 110, 112 (D. Mass. 1996) (court must indulge all inferences favorable to nonmoving party). The trial court's task is “carefully limited to discerning whether there are any genuine issues of material fact to be tried, not to deciding them.

Its duty, in short, is confined at this point to issue-finding; it does not extend to issue resolution.”

B.F. Goodrich v. Betkoski, 99 F.3d 505, 522 (2d Cir. 1996).

Here, the FTC’s own submissions make clear that there are far too many open issues of disputed fact to warrant summary judgment. “The depositions alone contain disputed crucial issues sufficient to require resolution at trial.” *Stepanischen v. Merchants Dispatch Trans. Corp.*, 722 F.2d 922, 930 (1st Cir. 1983). As in *FTC v. P.M.C.S., Inc.*, the DMC Defendants dispute, among other issues, the extent which they participated in the alleged violations, whether consumers were actually misled by the subject advertising, the extent of any consumer injury caused by any violations, whether they had actual knowledge that the alleged activities were improper, their control over the alleged activities, and the proportion of any injury for which they are responsible. Consequently, “material issues of fact permeate this dispute, precluding summary judgment in favor of the FTC.” 21 F.Supp.2d at 192. *See also Stepanischen*, 722 F.2d at 930 (“[w]here as here, the record makes plain that a genuine issue of material fact is still in dispute, it has often been thought not ‘appropriate’ to grant summary judgment”).

A. TRIABLE ISSUES OF FACT EXIST CONCERNING THE DMC DEFENDANTS’ LIABILITY FOR THE FTC’S CLAIMS

In evaluating the substantial issues of fact disputed by the DMC Defendants in connection with the advertising challenged by the FTC, it is important to keep in mind the view expressed by the United States Congress in connection with the Dietary Supplement Health and Education Act (“DSHEA”), concerning dietary supplements:

2. the importance of nutrition and the benefits of dietary supplements to health promotion and disease prevention have been documented increasingly in scientific studies;
- 3(A). there is a link between the ingestion of certain nutrients or dietary supplements and the prevention of chronic diseases such as cancer, heart disease and osteoporosis;

5. preventative health measures, including education, good nutrition, and appropriate use of safe nutritional supplements will limit the incidence of chronic diseases, and reduce long-term health care expenditures;
7. there is a growing need for emphasis on the dissemination of information linking nutrition and long-term good health;
8. consumers should be empowered to make choices about preventive health care programs based on data from scientific studies of health benefits related to particular dietary supplements;
12. the nutritional supplement industry is an integral part of the economy of the United States;
13. although the Federal Government should take swift action against products that are unsafe or adulterated, the Federal Government should not take any actions to impose unreasonable regulatory barriers limiting or slowing the flow of safe products and accurate information to consumers ...
14. dietary supplements are safe within a broad range of intake, and safety problems with the supplements are relatively rare; and
- 15(B). a rational Federal framework must be established to supersede the current *ad hoc* patchwork regulatory policy on dietary supplements.

21 U.S.C.A. § 321, at p.169, Congressional Finding Nos. 2, 3(A), 5, 7, 8, 12, 13, 14, and 15(B).

See, e.g., Nutritional Health Alliance v. Shalala, 953 F. Supp. 526, 528 (S.D.N.Y. 1997)

("agencies of government charged with promoting the food supply and the rights of consumers have paradoxically limited the information to make healthful choices in an area that means a great deal to over 100 million people"); *Inbata Specialty Chem. v. United States*, 366 F.Supp.2d 1358, 1363 n.9 (Ct. Int'l Trade 2005) (DSHEA "was intended to ease access to alternative therapies"). Under this framework, the FTC's claim that it has overcome all disputed facts concerning the challenged advertising must be rejected. Rather, a trial is required to fully evaluate the challenged advertising, the context and content of that advertising in light of the First Amendment and Congressional mandates, and the role of the DMC Defendants in the advertising.

1. The FTC Has Failed to Meet Its Burden Of Providing Evidence That Consumers Were In Fact Misled

Despite the FTC's arguments to the contrary, the challenged infomercials do not make any express claims other than that proper nutrition is important for the body to be able to respond to and avoid disease and that the ingredients in coral calcium and Supreme Greens are part of that proper nutrition. Nonetheless, the FTC argues, without evidence, that consumers were in fact misled by the subject infomercials because the infomercials affirmatively state that these products cure cancer, diabetes and other diseases.² The FTC, however, has not put before the Court in connection with its motion for summary judgment *any* complaint, affidavit or other representation by any consumer stating that they were actually misled by the subject advertisements.³

Commercial speech, like the challenged infomercials in this case, is protected by the First Amendment, absent evidence that it is false, deceptive or misleading. *FTC v. Brown & Williamson Tobacco Corp.*, 778 F.2d 35, 43 (D.C. Cir. 1985). Accordingly, to establish a claim that accurate statements of a particular speaker's beliefs violate the FTC Act, the FTC must prove that the challenged advertisement has the tendency to actually deceive consumers. *See Brown & Williamson*, 778 F.2d at 40 & n.2. To meet this burden, proof that the challenged advertisement "actually conveyed the implied message and thereby deceived a significant portion of the recipients [is] critical." *William H. Morris Co. v. Group W, Inc.*, 66 F.3d 255, 258 (9th Cir. 1995). *See also FTC v. Marketing Response Group, Inc.*, 1996 WL 420865 (M.D. Fla. 1996) (FTC must demonstrate that advertisement would be misleading to consumers acting

² No such claims actually exist in the infomercials. Rather, the entirety of the infomercials express nothing more than the guests' opinions, based upon each guest's review of the relevant scientific literature and their own experiences. No express claims of any kind concerning the subject dietary supplement and any particular disease is made at any time.

³ As recognized in *FTC v. Garvey*, 383 F.3d at 901, the FTC carries "the burden of proving that the express or implied message conveyed by the advertising in question was actually false." *See Enforma*, 362 F.3d at 1217 n. 14; *FTC v. Publishers Clearing House, Inc.*, 104 F.3d 1168, 1170 (9th Cir. 1997) (burden of proving falsity or deception is upon the FTC).

reasonably under the circumstances). As a result, the FTC cannot simply assert that an advertisement is understood in a particular way and is therefore misleading. It must present “evidence of substance about what the person to whom the advertisement is addressed finds to be the message.” *Brown & Williamson*, 778 F.2d at 40. See *Bellsouth Advertising & Publishing Corp. v. Lambert Publishing*, 45 F.Supp.2d 1316, 1324 (S.D. Ala. 1999) (plaintiff “must show actual deception by using reliable consumer or market research”). In short, the FTC cannot meet its summary judgment burden by simply stating that an advertisement is misleading to consumers. It must provide supporting evidence that consumers were in fact misled.

Here, the FTC has failed to provide a single consumer affidavit or market study that demonstrates that the subject infomercials are actually misleading to consumers. See *Brown & Williamson*, 778 F.2d at 40-41 (noting that typical evidence submitted to demonstrate that advertising is misleading is a market research or consumer studies); *3M Innovative Props. Co. v. Dupont Dow Elastomers LLC*, 361 F.Supp.2d 958, 969 (D. Minn. 2005) (proof in the form of consumer studies is “critical”). Absent this evidence, the FTC cannot meet its burden of demonstrating there is no issue of disputed fact on a critical, and *prima facie*, element of its claim. In *Herman Miller, Inc. v. Palazzetti Imports & Exports, Inc.*, 270 F.3d 298 (6th Cir. 2001), for example, the court concluded that isolated examples of potential confusion are insufficient to establish that a statement has the tendency to mislead.⁴ In that case, the plaintiff brought an action for false advertising under the Lanham Act against a competing furniture store. Granting judgment to the defendant, the Sixth Circuit held that the plaintiff had not demonstrated that the representations made by the defendant were actually misleading because, among other

⁴ To better understand the burden on the FTC to establish that the challenged advertisement has the capacity to mislead consumers, courts often look to the standards under the Lanham Act. See *Brown & Williamson*, 778 F.2d at 40 n.2 (“Owing to the paucity of cases involving *de novo* trial court proceedings under the FTC Act, we look to the Lanham Act cases for guidance as to evidentiary requirements to establish tendency to deceive”).

things, it relied upon only two customer letters, and did “not provide any consumer surveys to support its false advertising claims.” *Id.* at 323. *See Bellsouth Advertising*, 45 F.Supp.2d at 1324 (plaintiff “must show how consumers *actually* react to a statement”). Here, the FTC has not even put in the record *one actual consumer complaint* stating that the advertising is actually perceived to be misleading by consumers. Although a few customer complaints would still be insufficient, the complete lack of any such evidence by consumers alone defeats summary judgment.

The FTC’s attempt to condemn the subject infomercials without evidence that the claims are actually perceived by consumers as misleading runs afoul of the First Amendment and DSHEA. It is well established that the First Amendment protects both political and commercial speech. *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748 (1976). Critically, commercial speech is not “so removed from any ‘exposition of ideas’ and from ‘truth, science, morality and arts’” that it lacks all protection under the First Amendment. *Id.* at 762. To the contrary, the Court has recognized that consumers have at least as great an interest in receiving commercial information as information disseminated in the “most urgent political debate.” *Id.* at 763. As such, the Supreme Court has “rejected the ‘highly paternalistic’ view that government has complete power to suppress or regulate commercial speech.” *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm’n*, 447 U.S. 557, 562 (1980). In fact, the Court has noted an “alternative” to this paternalistic approach: “That alternative is to assume that this information is not itself harmful, that people will perceive their own best interests if only they are well informed, and the best means to that end is to open the channels of communication rather than to close them.” *Virginia State Bd. of Pharmacy*, 425 U.S. at 770. *See American*

Optometric Assoc. v. FTC, 626 F.2d 896, 908 (D.C. Cir. 1980) (rejecting highly paternalistic approach to suppression of speech).

Because of the constitutional protections afforded commercial speech, the FTC must carry its burden of demonstrating that the speech is in fact misleading to consumers through competent and credible evidence, not simply its own unsupported supposition. In *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), for example, the court held that conclusory assertions by the FDA that certain dietary supplement claims were misleading would not overcome the First Amendment protections afforded that speech. In reaching this conclusion, the Court of Appeals cited the Supreme Court's decision in *Ibanez v. Florida Dep't of Prof'l Reg.*, 512 U.S. 136, 146 (1994), in which the Court stated: "If the protections afforded commercial speech are to retain their force, we cannot allow rote invocation of the words 'potentially misleading' to supplant the [government's] burden to demonstrate that the harms it recites are real." Here, the FTC has failed to meet that burden with competent evidence, requiring denial of the motion for summary judgment.

2. **Triable Issues Of Fact Exist Concerning the Coral Calcium Infomercial**

Significant and material issues of fact exist concerning the DMC Defendants' liability in connection with the coral calcium infomercial. As recognized by the FTC, the DMC Defendants do not appear anywhere in the coral calcium infomercial, which features non-parties Kevin Trudeau and Robert Barefoot. In addition, the infomercial expresses only the previously published and widely disseminated opinions of Barefoot concerning coral calcium and its possible health benefits, which are clearly identified as Barefoot's opinions and not statements of

fact.⁵ These opinions mirror several books published by Barefoot, which contain numerous citations to scientific studies and journals. These citations to medical journals, scientific publications and related studies have never been challenged by the FTC as fictitious or nonexistent. Rather, the FTC has simply contended that it does not agree with the import of these citations or Barefoot's interpretation of them. In light of Congress' and the Supreme Court's express statement that information should not be withheld from consumers, but consumers should be entitled to make their own choices regarding dietary supplements, the conflicting evidence, including the conflicting scientific evidence supporting the claims in the advertising, creates issues of fact that prevent summary judgment. *See, e.g., FTC v. Enforma Natural Prods., Inc.*, 362 F.3d at 1208 (reversing district court's grant of injunction where FTC misapplied its own standard and a genuine dispute existed as to the substantiation for the product and the reasonableness of the defendants' reliance).

a. Disputed Issues Exist Regarding the Role and Reasonableness of the DMC Defendants' Conduct In Connection with the Coral Calcium Infomercial

The DMC Defendants strongly dispute that they had a central role in the production and dissemination of the coral calcium infomercial. To the contrary, the evidence in the record, including the record submitted by the FTC, makes clear that non-party Kevin Trudeau produced the infomercial, and Allen Stern and his companies paid for the majority of the costs associated with the infomercial, disseminated the infomercial, had ultimate decision-making authority over the infomercial, purchased all of the products sold through the infomercial, delivered products to consumers and received all customer funds. As set forth in *FTC v. P.M.C.S., Inc.*, these disputed

⁵ The FTC recognizes that the DMC Defendants do not themselves make any claims about any of the subject products. Rather, the claims are solely those of the guest on the show. *See FTC v. Garvey*, 383 F.3d at 901-903 (recognizing distinction between the person actually making the claim and participants).

issues of fact concerning the level of involvement of the various defendants preclude summary judgment. 21 F.Supp.2d at 191.

In addition to its limited role in the production and dissemination of the coral calcium infomercial, the substantiation relied upon by the DMC Defendants in connection with the infomercial was reasonable.⁶ In *FTC v. Garvey*, for example, the Ninth Circuit held that a participant in allegedly misleading advertising may provide a complete defense to the FTC's claims if the participant could demonstrate that he or she relied upon "some relevant substantiation for the advertising claims made." 383 F.3d at 902. In that case, Steve Garvey claimed that he relied upon two booklets supplied by the manufacturer, Enforma Natural. These booklets contained several citations to scientific studies. The FTC challenged these booklets, pointing out alleged flaws in the books and the fact that the books did not specifically identify or support all of the claims made in the advertisement. The Ninth Circuit rejected the FTC's attempt to cherry-pick issues from the booklets, finding that even though the booklets did not mention certain ingredients explicitly, "the booklet provides some relevant substantiation for the advertising claims made." 383 F.3d at 902.

Here, the DMC Defendants have testified that they each reviewed Barefoot's books *The Calcium Factor* and *Death By Diet* prior to any involvement in acting as a phone center in connection with the coral calcium infomercial. These books contain numerous citations to scientific studies, journals and literature. Undoubtedly, the books authored by Barefoot contain far more scientific support and citation than the booklets challenged in the *Garvey* case. In addition, Barrett has testified that his father took coral calcium after being diagnosed with

⁶ The FTC's own guidelines for dietary supplement advertising make clear that all that is required is a "reasonable basis" to make certain claims, supported by competent and reliable scientific evidence. See *Dietary Supplements: An Advertising Guide for Industry*, (the Guide can be found on the FTC's website at <http://www.ftc.gov/bcp/online/pubs/buspubs/dietsupp.htm#llb>.)

cancer, and Barrett has testified that he genuinely believes that the product has been a factor in his father's recovery. Thus, as was the case with Garvey, Barrett "had first-hand anecdotal evidence of the efficacy [of coral calcium] and had information that purported to present scientific bases for [the] claims." *Garvey*, 383 F.3d at 902. As the Ninth Circuit held, this substantiation was sufficient to avoid liability. At a minimum here, the level of substantiation given the defendants' role creates a triable issue of fact that defeats summary judgment.

b. The FTC's Claims May Be Barred By *Res Judicata*

The FTC disputes the DMC Defendants' assertion of a limited involvement in the coral calcium infomercial, and argues that the DMC Defendants were central players, if not co-conspirators in the production and dissemination of the program. Were the FTC able to prove such a conspiracy, however, its claims would likely be barred by *res judicata*. Specifically, the doctrine of *res judicata* provides that "a final judgment on the merits of an action precludes the parties or their privies from relitigating issues that were or could have been raised in that action." *Massachusetts School of Law at Andover, Inc. v. American Bar Assoc.*, 142 F.3d 26, 38 (1st Cir. 1998). The doctrine of *res judicata* applies when the following requirements are met: (1) there is a final judgment on the merits; (2) the prior action involves the same parties or their privies; and (3) the subsequent litigation involves the same transactions or connected transactions that could have been asserted in the first action. *Id.* See also *Aunyx Corp. v. Cannon U.S.A., Inc.*, 978 F.2d 3, 6 (1st Cir. 1992) (citing *Kale v. Combined Insurance Co. of America*, 924 F.2d 1161, 1165 (1st Cir.), *cert. denied*, 502 U.S. 816 (1991)); *Connaughton v. New England Tel. & Telegraph*, 1988 WL 34321, at *4-5 (D. Mass. Mar. 18, 1988).

Here, there is no dispute that the FTC filed a case in the United States District Court for the Northern District of Illinois against both Robert Barefoot and Kevin Trudeau concerning their involvement in coral calcium infomercials over a year before the present action was filed in